REMARKS/ARGUMENTS

This is in response to the official action of April 27, 2007. Claim 20 has been amended to further define the nature of the catheter shaft and its degree of flexibility as well as its relation to the vasculature and myocardium. Additionally, claim 20 has been amended to reflect changes in its syntax and not affecting its scope. Claim 21 has been amended for accuracy. Claims 33-38, newly presented in a previous amendment, have been canceled as they are considered to be redundant of the remaining claims. Such cancellation should not be considered as a relinquishment of scope.

THE INVENTION

Applicants' invention, as now defined by the claims, relates to a catheter for implanting one or more pellets containing therapeutic agent within myocardial tissue. The catheter includes an elongate flexible body of sufficient length and flexibility to be advanced transluminally through the patient's vasculature to the patient's heart. A delivery chamber is coupled to the distal end of the catheter body and includes a chamber for carrying a plurality of sequentially positioned pellets, the pellets containing a therapeutic agent. The distal end of the chamber includes a port through which the pellets may be released. The catheter also includes an actuator that is coupled between a control at the proximal end of the catheter and, at its distal end, to the delivery chamber, so that pellets can be urged, in sequence, through the port. The distal end of the chamber is configured and adapted to penetrate the wall of the heart so that one or more pellets carrying the therapeutic agent can be implanted in the myocardium. The pellets may be in the form of minispheres or may be provided with a pointed shape.

THE CITED REFERENCES

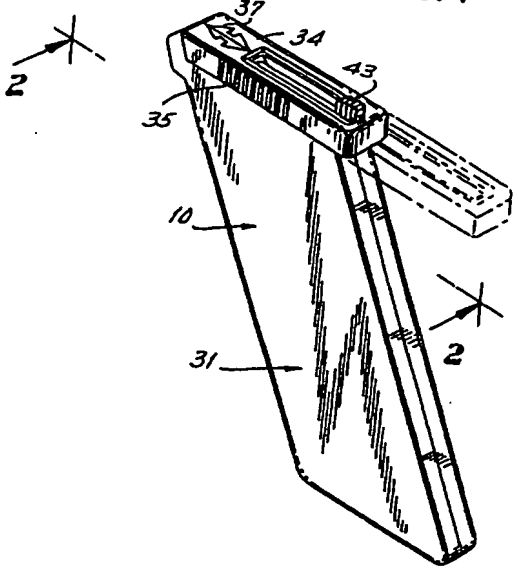
U.S. Patent 2,269,963 (Wappler)

Wappler '963 discloses a device for implanting small solid bodies, such as rod-like "radium seeds" for treatment of cancerous growths and the like. The device is generally pistol-like and has a rigid needle-like tube having a sharp beveled end adapted to pierce flesh. The seeds are carried within the tube and are urged outwardly of the tube by a plunger. The action of April 27, 2007 acknowledges that Wappler fails to disclose a device with a flexible body.

U.S. Patent Re 34,936 (Campbell)

Campbell '936 describes a device for implanting an identifying solid marker beneath the skin of the laboratory animal. The device includes an implanting instrument 10 (FIG. 1) into which a needle assembly 19 (FIG. 13) can be loaded. The needle assembly is illustrated in FIGS. 13 and 15, reproduced below.

FIG. 1



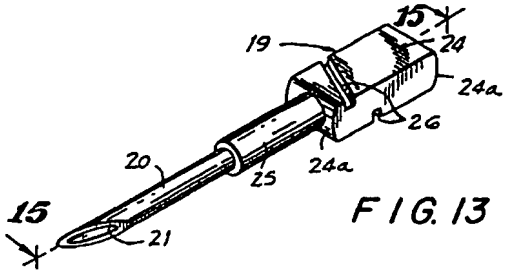
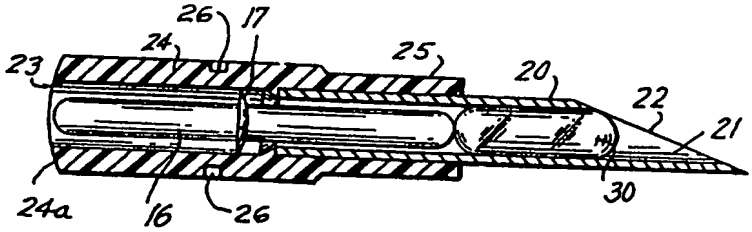


FIG. 13

FIG. 15



With a marker loaded in a needle, the needle is loaded into the instrument, the animal is immobilized and the needle then is inserted percutaneously. The instrument then is actuated to cause a plunger to drive the marker out of the needle into the animal, after which the device can be removed from the animal and the needle removed. The instrument then is ready to receive another needle to implant a marker in another animal.

The replaceable needle assemblies include a rigid stainless steel tubular needle 20 having a sharp distal tip and an exit opening 21. The proximal end of the tubular needle 20 is secured to a plug 24 having various surfaces and grooves by which the needle is detachably secured to the instrument. The proximal portion of the needle includes an outer rigid sleeve 25. The distal end of the sleeve 25 serves as a guide to assure placement of the marker at a desired position beneath the skin. (5:33-36). The tube 20, the sleeve 25 and plug 24 are all formed from rigid materials. (4:10-17).

U.S. Patent 4,457,712 (Dragan)

Dragan discloses a dental syringe having a barrel and a plunger, intended to extrude root canal resin into a root canal. The device is generally pistol-like, and includes a reservoir for holding the resin, a plunger, a ratchet pawl and a needle for dispensing the resin.

THE REJECTIONS

Claim Rejections – 35 U.S.C. §103

Reconsideration is requested of the rejection of claims 20-27 and 29-32 as unpatentable over the combined disclosures of Wappler and Campbell. The rejection fails to demonstrate how the combination of Wappler and Campbell would have rendered obvious the subject matter of applicants' claims where neither of those references discloses features of the claimed combination as discussed below. Where neither reference makes such disclosure, it is not seen how their combination can do so.

More particularly, the action acknowledges that Wappler does not disclose an elongate flexible catheter body. Additionally, the claims include the limitation that the catheter body must be of a length to allow for transluminal delivery through a patient's vasculature to a targeted region of the myocardium. Wappler may be likened to a hypodermic needle that pierces the skin and enters into the body in a straight line to deliver radium seeds at a selected depth. Campbell discloses a similar type of device having a needle assembly that is detachable connectible to an instrument that serves as a driving mechanism to deliver an animal marker. The device includes detachable needles. The needles are rigid and include a sharp tissue piercing tip. Each needle has at its proximal end, a rigid plastic structure. Neither the needle nor the rigid plastic structure (including the sleeve 25 and plug 24 is flexible nor is there any reason for any of them to be flexible. Additionally, neither Wappler nor Campbell is capable of being delivered transluminally through a patient's vasculature to a target region of the myocardium.

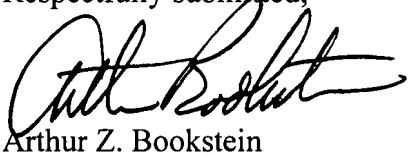
To the extent that the rejection is based on the notion that anything made out of "plastic" is necessarily "flexible" or that "flexible" is a broad term without additional reference, such interpretation is unreasonable. Elements 24 and 25 in Campbell necessarily are rigid whether made of plastic or any other material. There is no reason for them not to be rigid and, indeed, where they serve to secure the position of the needle in the instrument, rigidity would seem to be

essential. Campbell itself states that these elements must be rigid. Moreover, the fact that the body 25 is mounted on and about a rigid needle further demonstrates the necessity that the sleeve 25 is not flexible. In any case, the sleeve 25 is a relatively short tubular element that serves as a stop to contact the animal's skin for gauging purposes. It has nothing to do with an elongate flexible catheter. Such interpretation ignores applicants' disclosure and the purpose of applicants' invention and is an unreasonable interpretation.

Each of claims 21-30 depends from claim 20 and is patentable over Wappler and Campbell for the same reasons. Additionally, claim 22 includes the further limitation of a steering mechanism for turning the distal end of the body to allow the delivery chamber to be selectively guided through a body lumen. Notwithstanding the actions referenced to "handle 37" manipulation of that handle can only serve to manipulate the entire device, not to steer the distal end of the device apart from more proximal regions. Claim 31 depends indirectly from claim 20 and is patentable for the same reasons.

Reconsideration is requested of the rejection of claim 28 as unpatentable under 35 U.S.C. §103 in view of the combined disclosures of Wappler and Dragan. Dragan fails to disclose or suggest those features of applicants' invention that are missing from Wappler, as discussed above. The rejection should be withdrawn.

Respectfully submitted,



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Date: October 29, 2007